UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,313	09/24/2001	Gunther Berndl	0050/49860	8414

26474 7590 05/28/2009

NOVAK DRUCE DELUCA + QUIGG LLP
1300 EYE STREET NW
SUITE 1000 WEST TOWER
WASHINGTON, DC 20005

EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
05/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/937,313
Filing Date: September 24, 2001
Appellant(s): BERNDL ET AL.

Michael P. Byrne
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/26/09 appealing from the Office action mailed 5/28/08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,127,422	GUZI et al	11-1978
5,858,412	STANIFORTH et al	01-1999
6,086,915	ZELIGS et al	07-2000

6,066,334 KOLTER et al 05-2000

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10-12, 14-18, 20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Guzi Jr. et al (USPN 4,127,422 hereafter '422) in view of Staniforth et al (USPN 5,858,412 hereafter '412) or Zeligs et al (USPN 6,086,915 hereafter '915).

The claims are drawn to a process for making an excipient comprising spray drying a composition comprising 10-50% of a surfactant and a vinylpyrrolidone polymer.

The '422 patent teaches a method of making an excipient comprising spray-drying a solution comprising 15-40 % by weight of a nonionic dispersing agent, and a polymer such as N-vinylpyrrolidone (col. 2, lin. 20-60). The nonionic dispersing agents have an HLB greater that 11, specifically from 12-18 (col. 3, lin. 5-10). The N-vinylpyrrolidone has a K-value from 15-21 (example 9). The excipient comprises a pigment (examples). The formulation is also processed with a concentration of water that is removed during processing to result in a dry powder

material (claims). After spray drying the powders are ground through a 1/16-inch (12-mesh) screen (examples). This would indicate that particles were roughly as large as 1586 microns are present in the final product. However since smaller particles must also be present in order to have fit through the mesh screen. It is the position of the Examiner that some if not most of the particles would be with within the range of the instant claims. It would be obvious to one of ordinary skill in the art to found particles ranging from 10 microns to 1 mm in the resulting free flowing excipient given the spraying and grinding techniques disclosed in the reference and known in the art.

Regarding the drop point of claim 11, although the reference is silent to a specific drop point, the reference teaches surface-active compounds that are similarly identified in Applicant's specification. As such all of the inherent properties such as drop point are encompassed by the surfactants of the '422 patent. The instant specification identifies polyoxyethylene ethers and fatty acids as useful in the invention. These are all disclosed by the prior art. It is the position of the Examiner that these polymers would inherently meet the limitations of the claims.

The surfactants can be selected from the group consisting of ethoxylated fatty acid esters and polyoxyethylene fatty glycerides (col. 3, lin. 30-40). The reference does not disclose the specific surfactant so of claims 15 or 16 yet suggest similar polymers in similar concentrations. The inclusion of these surfactants into microparticulate formulations is well known in the art as can be seen in the '412 and '915 patents.

The '412 patent discloses microparticulate formulation comprising various surfactants including polysorbate 40, an ethoxylated sorbitan fatty acid ester (col. 11, lin. 25-30), in a concentration up to 20% (col. 13, lin. 47-52, claim 24). The particles are spray dried (col. 14,

lin. 35-39). The resulting particles measure from 10-500 microns (col. 14, lin. 58-64). The formulation further comprises up to 50% adjuvants such as polyvinylpyrrolidone (col. 18, lin. 53-58). It would have been obvious to include the surfactants of the '415 patent in order to improve the compressibility of the resulting microparticles.

The '412 patent also suggests the inclusion of castor oil derivatives as possible surfactants (col. 11, lin. 34). The inclusion of specific castor oil derivative are well known in the art as seen in the '915 patent. The '915 patent disclose a microparticle carrier formulation comprising 10-40% polyvinylpyrrolidone and 5-20%, an ethoxylated castor oil (col. 12, lin. 35; col. 16, lin. 17-27). The skilled artisan would have been motivated to include the surfactants of the '415 patent in order to improve the stability of the spray dried particles as well.

One of ordinary skill in the art would have been motivated to combine the surfactants of the '415 and '915 patents in order to provide improved stability and compressibility of the microparticles resulting from the spray drying. It would have been obvious to combine these components in order to provide an improved method of making a carrier composition with improved stability.

Claims 10, 15, 16, 18, 20 and 21 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Kolter et al (USPN 6,066,334 hereafter '334) in view of Staniforth et al (USPN 5,858,412 hereafter '412) or Zeligs et al (USPN 6,086,915 hereafter '915). The claims are drawn to a method of making an excipient comprising 10-50 % of a surfactant and a polymer of polyvinylpyrrolidone, wherein the formulation does not comprise a pigment.

The '334 patent discloses a redispersible microparticle formulation comprising polyvinylpyrrolidone and up to 10% of a surfactant including both ionic and nonionic surfactants (abstract; col. 3, lin. 32-35). The polyvinylpyrrolidone has K-values from 30-50 (col. 3, lin. 4-12). The resultant particles have an average size of 1000 microns and are spray-dried (example 1). The formulation further includes binders, lubricants and further bulking agents (col. 4, lin. 51-65), yet is free of pigments.

Although the reference indicates that the emulsifiers are present in a concentration up to 10%, they are not exemplified to this range. However the wide range of the concentration would be within the level of ordinary skill of an artisan to optimize in order to arrive at the presently claimed invention. The general conditions of the claims have been met, specifically a process for making an excipient comprising spray drying a composition comprising polyvinylpyrrolidone having K-values from 30-50, and at least 10% of a surfactant. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Regarding the specific surfactant/emulsifiers, it is the position of the Examiner that it would have been well within the level of skill in the art to simply substitute the emulsifiers/dispersing agents of the '412 and '915 patent into the '334 patent. The '34 patent discloses that both ionic and nonionic surfactants are useful in the invention.

The '412 patent discloses microparticulate formulation comprising various surfactants including polysorbate 40, an ethoxylated sorbitan fatty acid ester (col. 11, lin. 25-30), in a concentration up to 20% (col. 13, lin. 47-52, claim 24). The particles are spray-dried (col. 14, lin. 35-39). The resulting particles measure from 10-500 microns (col. 14, lin. 58-64). The formulation further comprises up to 50% adjuvants such as polyvinylpyrrolidone (col. 18, lin. 53-58). It would have been obvious to include the surfactants of the '415 patent in order to improve the compressibility of the resulting microparticles.

The '412 patent also suggests the inclusion of castor oil derivatives as possible surfactants (col. 11, lin. 34). The inclusion of specific castor oil derivative are well known in the art as seen in the '915 patent. The '915 patent disclose a microparticle carrier formulation comprising 10-40% polyvinylpyrrolidone and 5-20%, an ethoxylated castor oil (col. 12, lin. 35; col. 16, lin. 17-27). The skilled artisan would have been motivated to include the surfactants of the '412 patent in order to improve the stability of the spray dried particles as well.

One of ordinary skill in the art would have been motivated to combine the surfactants of the '412 and '915 patents in order to provide improved stability and compressibility of the microparticles resulting from the spray drying. It would have been obvious to combine these components in order to provide an improved method of making a carrier composition with improved stability.

(10) Response to Argument

Applicant argues that:

1) The combination of Guzi, Staniforth and Zeligs patents does not obviate the instant claims since;

a) The combination does not teach or disclose the spray drying of a solution

b) The combination could not be used for a solid pharmaceutical dosage form

c) The inclusion of a pigment is foreclosed by the claims since they must "consist essentially" of the components.

2) The combination of the Kolter, Staniforth and Zeligs patent do not obviate the instant claims since;

a) The combination does not teach or disclose the spray drying of a solution

b) The combination could not have been combined to arrive at the instant invention

c) The combination would have yielded predictable results

Regarding the first set of arguments it remains the position of the Examiner that combination of the Guzi, Staniforth and Zeligs continues to obviate the instant claims. First regarding the spray drying aspects of the Guzi patent, it remains the position of the Examiner that solution of similar composition is in fact spray dried. Each component of the composition is water dispersible. The composition of Guzi is further homogenized in order to arrive at a uniform mixture with little to no agglomeration or particles. The resultant mixture is spray dried and a free flowing polymer is achieved (claims 1-3). The mixture comprises the same components of the instant claims namely a copolymer of N-vinylpyrrolidone and a water soluble

surfactant (claim 2). Applicant argues that none of the supporting references disclose the spray drying of a solution, however the patent are relied upon for their disclosures of specific surfactants in the formation of particles. The Staniforth patent is used to for its disclosure of ethoxylated sorbitan fatty acid esters that were suggested by the Guzi patent as possible surfactants. The Guzi patent suggested discloses the inclusion of polyoxyethylene fatty glycerides. Though not disclosed these surfactants are suggestive of the inclusion of castor oil based surfactants, since ethoxylated castor oil and sorbitan fatty esters are species falling under the genus of polyoxyethylene fatty glycerides compounds. The Staniforth and Zeligs patents are used to support the inclusion of specific surfactants of the instant claims, under the teachings and suggestions of the Guzi patent. It would have been obvious to include these surfactants since they are similar to those disclosed in the Guzi patent and would be expected to perform similarly, namely providing a stable free flowing powdered excipient.

Regarding the "consisting essentially" language of the claims and whether this would foreclose the inclusion of the pigments required by the Guzi patent, it remains the position of the Examiner that such open claims language does not in any way foreclose the inclusion of the pigments required by the Guzi patent. Consisting essentially is used to exclude any components that would fundamentally change the characteristics of the resulting formulation. However a pigment being added to an excipient would only enhance the characteristics of the excipients, since it would be easily identifiable, and distinct from other excipients of the similar class. The pigment would further serve to identify any pharmaceutical dosage from using said pigment. The pigment of Guzi would be easily water soluble and useful in identification coatings for solid dosage forms. The pigments would help to define the excipient as unique among similarly

functioning tableting agents. However the intended use of the excipient "adapted for use in a solid pharmaceutical dosage form" is merely a future intended use limitation. Applicant is reminded that where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997). Also the selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). In the instant case, the Guzi patent discloses the pigments of the patent can be used in a wide variety of applications including coatings (col. 1, lin. 63). The ingredients are all generally recognized as safe and are used in pharmaceutical dosage forms as seen in the Staniforth and Zeligs patents.

For these reasons the combination of the Guzi, Staniforth and Zeligs patents continues to obviate the instant claims.

Regarding the second set of arguments it remains the position of the Examiner that the Kolter, Staniforth and Guzi patent continue to obviate the claims. Regarding the Kolter patent, it remains the position of the Examiner that mixture of the patent and the process for forming particles obviates the instant claims. The Kolter patent discloses a mixture comprising a copolymer of N-vinylpyrrolidone and a water soluble surfactant, spray-dried into a free flowing copolymer (example 1). Applicant argues that the patent spray -dries an emulsion and not a solution. However emulsifiers are added to the mixture creating a homogeneous s mixture of liquids (col. 3, lin. 30-45). This homogeneous mixture of liquids would effectively function identically to the instant claims. The resultant free dried powder would be free from pigment as

well. Again as discussed above the Staniforth and Zeligs patents are not relied upon to include the specific surface active substances of the instant claims. The Kolter patent discloses from 10-20 % of the formulation reserved for water soluble ionic and nonionic emulsifiers that aid the mixture (col. 3, lin. 30-35), yet is silent to the specific ethoxylated sorbitan fatty esters as described in the Staniforth and Zeligs patents. The surfactants would have acted to emulsify the insoluble polyvinyl acetate and reduce particle agglomeration effectively forming an easily sprayable solution (col. 3, lin. 30-45). Applicant argues that the results would not have been unexpected, however since it is the position of the Office that the process and compositions are the same, any results from the process would be similarly unexpected. Since a compound and its properties cannot be separated, it remains the position of the Examiner that since the same process is used to produce the same product any results that yield form the use of these free flowing excipients would be identical and similar unexpected as the instant claims.

For these reasons the claims remain obviated.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/MICAH-PAUL YOUNG/

Examiner, Art Unit 1618

Conferees:

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617